

# EXHIBIT L

# Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review

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## Abstract

**Introduction and hypothesis** This study describes the incidence, risk factors, and treatments of graft erosion, wound granulation, and dyspareunia as adverse events following vaginal repair of pelvic organ prolapse with non-absorbable synthetic and biologic graft materials.

**Methods** A systematic review in Medline of reports published between 1950 and November 2010 on adverse events after vaginal prolapse repairs using graft materials was carried out.

**Results** One hundred ten studies reported on erosions with an overall rate, by meta-analysis, of 10.3%, (95% CI, 9.7 –

10.9%; range, 0 – 29.7%; synthetic, 10.3%; biological, 10.1%). Sixteen studies reported on wound granulation for a rate of 7.8%, (95% CI, 6.4 – 9.5%; range, 0 – 19.1%; synthetic, 6.8%; biological, 9.1%). Dyspareunia was described in 70 studies for a rate of 9.1%, (95% CI, 8.2 – 10.0%; range, 0 – 66.7%; synthetic, 8.9%; biological, 9.6%). **Conclusions** Erosions, wound granulation, and dyspareunia may occur after vaginal prolapse repair with graft materials, though rates vary widely across studies.

**Keyword** Pelvic organ prolapse · Erosion · Dyspareunia · Granulation

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## Introduction

Pelvic organ prolapse (POP) affects up to one third of women [1]. Approximately 200,000 women undergo surgical correction of POP in the USA annually, and 29% of all procedures are repeat operations [2]. High recurrence rates of POP have led surgeons to seek more durable surgical interventions with the use of graft material to augment prolapse repairs. The Society of Gynecologic Surgeons (SGS) formed a Systematic Review Group to provide up-to-date systematic reviews and practice guidelines on important gynecological surgery topics. The first topic chosen was the use of graft materials in the transvaginal repair of POP. We have previously reported the findings of the systematic review and published the guidelines for use of graft materials in vaginal prolapse repair [3].

In the systematic review, several adverse events directly attributable to the use of graft material were identified including graft erosion, granulation tissue formation, and

dyspareunia/vaginal pain [3]. This is a more detailed report of these three adverse events. Our objectives were to identify and characterize the incidence, risk factors, and treatment of these adverse events after repair with synthetic and biological grafts.

## Materials and methods

A systematic review of all vaginal prolapse repair papers using graft materials published between 1950 and November 2007 was conducted by the Systematic Review Group of the Society of Gynecologic Surgeons. Studies were identified from a Medline search identifying terms including “vaginal or uterine prolapse,” “rectocele,” “cystocele,” “surgery of the pelvic floor,” “surgical mesh,” “vagina,” “rectum,” and “bladder”. We included studies published in any language that reported anatomical, symptomatic, or adverse event outcomes on any type of graft material in transvaginal pelvic organ prolapse repairs (excluding abdominal or laparoscopic graft use). Details regarding the search strategy employed and results have been previously published [3].

For the present study, we conducted a systematic review of the adverse events of graft erosion, wound granulation, and dyspareunia reported in all comparative studies or case series with at least 30 subjects in the graft arm, with no language restriction. Some of these studies were previously identified in the SGS systematic review, and that search was updated to include additional studies published between November 2007 and November 2010. All studies were reviewed for additional details regarding timing of diagnosis of the complication as related to the incident surgery in weeks, potential risk factors for the complication as outlined by the author, diagnostic approach including radiological evaluation and details reported regarding management. The original data extraction, performed for the full systematic review [3], was done by a single investigator and checked by at least one additional investigator. Additional data for this review were extracted by four investigators (HA, DDR, LL, and JLC) with each paper reviewed twice to assure accuracy of the data extraction. We defined graft erosion as exposed graft material in the vagina or surrounding pelvic organs. For graft erosion treatment, we specifically captured details about the use of vaginal agents and the need for additional surgeries or procedures. In addition, we captured whether the procedure to remove the graft was performed in the office or operating room. Granulation tissue was defined as the formation of granulation tissue at the site of graft placement, and we included all reported cases of de novo dyspareunia; otherwise, we reported on persistent dyspareunia after surgery.

We performed meta-analyses of the adverse event rates of cohorts of women receiving the same graft material using the DerSimonian and Laird random effects model [4]. Meta-analyses were restricted to the two most commonly used graft materials (non-absorbable synthetic and biological graft). Since most studies evaluated adverse event rates in cohorts of women all receiving the same graft material (as opposed to comparative studies), we performed indirect comparisons across studies of adverse event rates. We compared the summary adverse event rates of studies using the two graft materials with *t* tests. Statistical heterogeneity, a measure of whether differences in reported effects were due to chance, was tested with the *Q* statistic (significant when  $p < 0.10$ ) and quantified its extent with *I* [2, 5]. Since this study was a systematic review, it was exempted from human research review committee approval.

## Results

The initial Medline search identified 2,260 citations. After abstract screening, 196 full text articles were assessed in detail; 74 papers described the use of vaginal graft materials for the repair of POP. Of these, 58 studies reported on any adverse events, 49 of which (66% of all graft articles) included specific information regarding graft erosions, wound granulation, or dyspareunia. We updated that search to include additional studies published between November 2007 and November 2010. There were another 1,269 citations, and we identified 101 additional papers describing the use of vaginal graft material with at least 30 subjects in the mesh arm. From these papers, 77 additional studies reported on these adverse events.

### Graft erosion

Graft erosion was documented in 110 studies after excluding one study that reported only summary adverse event rates across a variety of different graft materials [6] and two studies that used absorbable synthetic graft (polyglactin-10) [7, 8]. The 110 studies included 11,785 women and had a summary incidence of 10.3% (95% CI, 9.7 – 10.9%; range, 0 – 29.7%; Table 1, Figs. 1 and 2). The studies were statistically heterogeneous in their graft erosion rates. We evaluated study-level differences such as graft type, publication year, and sample size, and none of these factors adequately explained the heterogeneity among the studies. Similar erosion rates occurred after use of synthetic (10.3%, 91 studies,  $N = 10,440$ ) and biological grafts (10.1%, 19 studies,  $N = 1,345$ ). The reported timing of diagnosis of graft erosion ranged from 6 weeks to 12 months.

**Table 1** Comparison of rates of adverse events between non-absorbable synthetic and biological graft

Adverse event graft type	Number of studies	Total number of adverse events/total number of patients	Summary adverse event rate <sup>a</sup> (95% confidence interval) (%)	P difference (subgroups)
Graft erosion				
All grafts	110	982/11,785	10.3 (9.7, 10.9)	
Non-absorbable synthetic	91	897/10,440	10.3 (9.7, 11.0)	NS
Biologic	19	85/1,345	10.1 (8.3, 12.3)	
Wound granulation tissue formation				
All grafts	16	92/1,762	7.8 (6.4, 9.5)	
Non-absorbable synthetic	9	49/1,113	6.8 (5.2, 8.9)	NS
Biologic	7	43/649	9.1 (6.8, 12.1)	
Dyspareunia				
All grafts	70	350/5,638	9.1 (8.2, 10.0)	
Non-absorbable synthetic	54	284/4,566	8.9 (8.0, 10.0)	NS
Biologic	16	66/1,072	9.6 (7.6, 12.1)	

NS statistically non-significant ( $p > 0.05$ )

<sup>a</sup> Calculated by meta-analysis

Fourteen studies reported on potential risk factors for graft erosion [9–22]. The most commonly cited potential risk factors was concomitant hysterectomy, but other potential risk factors included patient age, surgeon experience, the use of inverted “T” colpotomy incisions, smoking, and diabetes mellitus.

Graft erosion symptoms included vaginal discharge, odor, vaginal pain, dyspareunia, or pain experienced by the sexual partner. Management of graft erosions in non-absorbable synthetic graft was reported in 76 studies, involving 795 women: 165 (21%; pooled, not meta-analyzed, estimate) were successfully treated with estrogen or antiseptic agents, 87 (11%) were successfully treated with excision in the surgeon’s office, and 448 (56%) were treated with surgical excision in the operating room, with some women requiring two to three additional surgeries to resolve symptoms. Regarding management of erosion in biological graft, this was reported for 35 of 63 (56%) women from 12 studies with half of these patients responding to local treatment with topical agents without the need for surgical revision.

#### Wound granulation

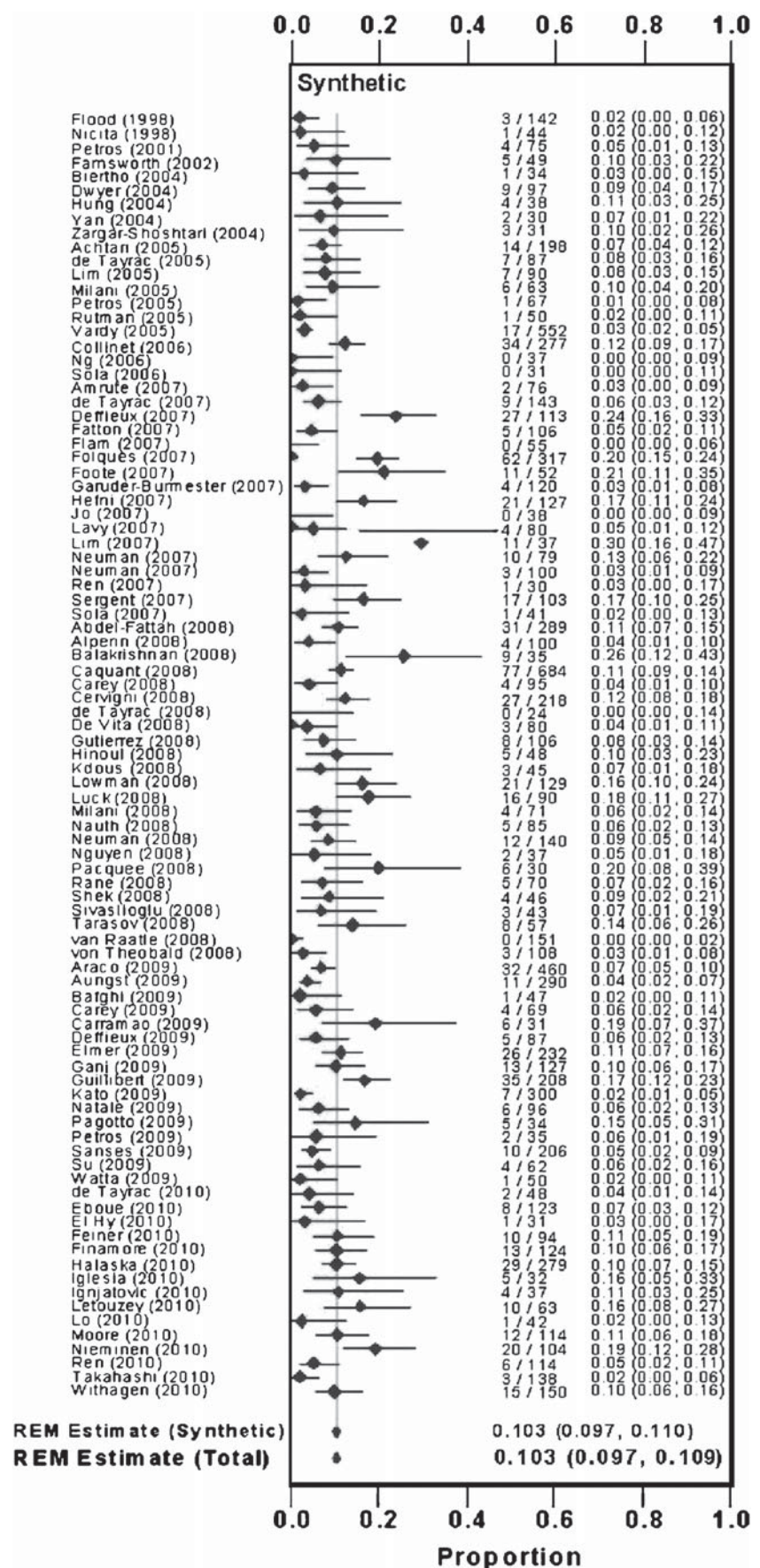
Wound granulation was reported in 17 papers, including one study that used a variety of different graft materials [7] and was not included in the meta-analysis. The overall incidence of granulation tissue in the remaining 16 studies was 7.8% (95% CI, 6.4–9.5%; range, 0–39%,  $N = 1,762$ ; Table 1, Fig. 3). The studies were statistically heterogeneous in their wound granulation rates. No specific factor adequately explained the heterogeneity

among studies, and the rate of wound granulation in the seven studies that used biological grafts was higher (9.1%) than in the nine studies of non-absorbable synthetic graft (6.8%), but this difference did not reach statistical significance. One paper reported that wound granulation occurred within 8 weeks of surgery [23], and another paper reported that graft placement with permanent braided sutures was a risk factor for wound granulation [7]. Two papers reported treatment approaches to wound granulation; one paper reported spontaneous resolution [23], and another reported resolution with suture removal and application of silver nitrate [24].

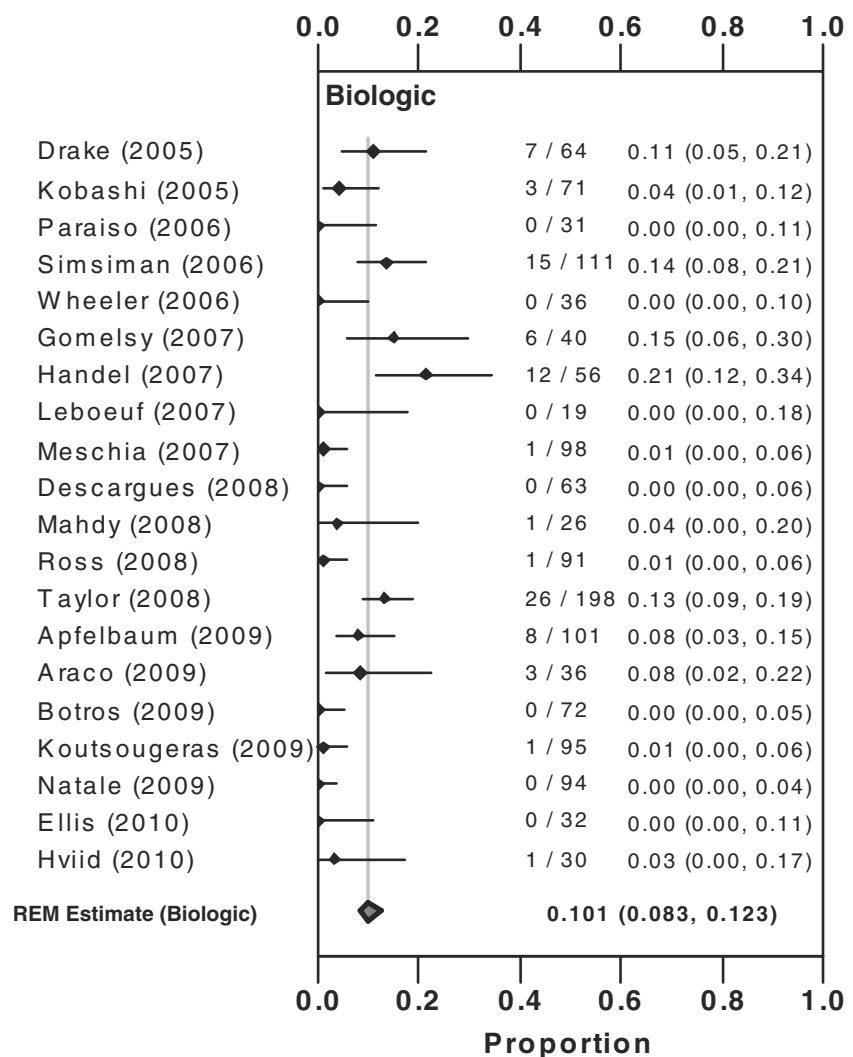
#### Dyspareunia

Dyspareunia was reported in 71 papers, including one study of absorbable synthetic grafts [8] that was excluded from meta-analysis. The overall incidence in the remaining 70 studies was 9.1% (95% CI, 8.2–10.0%; range, 0–66.7%;  $N = 5,638$ ; Table 1, Figs. 4 and 5). The studies were statistically heterogeneous in their reporting on the incidence of dyspareunia. No specific factor adequately explained the heterogeneity among studies. A similar incidence of dyspareunia occurred after use of synthetic (8.9%, 54 studies) and biological grafts (9.6%, 16 studies). There was a lack of consistency in reporting whether the population analyzed for dyspareunia was restricted to sexually active patients or included entire study populations. Cited risk factors in five papers included posterior repair [10, 11, 24] and mesh erosion [25, 26]. In two papers, treatments included the use of vaginal estrogen cream [10] or excision of mesh erosions [25].

**Fig. 1** Rates of graft erosion after non-absorbable synthetic graft. Studies of women receiving non-absorbable synthetic grafts for vaginal prolapse in which adverse event rates were reported. For each study, the proportion and 95% confidence interval of women with the outcome are plotted. The *diamond* indicates the overall proportion of women with the outcome across the studies by random effects model meta-analysis



**Fig. 2** Rates of graft erosion after biological graft. Studies of women receiving biological grafts for vaginal prolapse in which adverse event rates were reported. For each study, the proportion and 95% confidence interval of women with the outcome are plotted. The *diamond* indicates the overall proportion of women with the outcome across the studies, by random effects model meta-analysis



## Discussion

In our original systematic review [3], we reported the anatomical and symptomatic efficacy of treating prolapse using graft augmentation and described the incidences and spectrum of adverse events associated with grafts placed vaginally. In this current analysis, a more detailed accounting is made of three adverse events: graft erosions (10.3%), wound granulation (7.8%), and dyspareunia (9.1%). Reported risk factors and treatment strategies for these three adverse events varied widely.

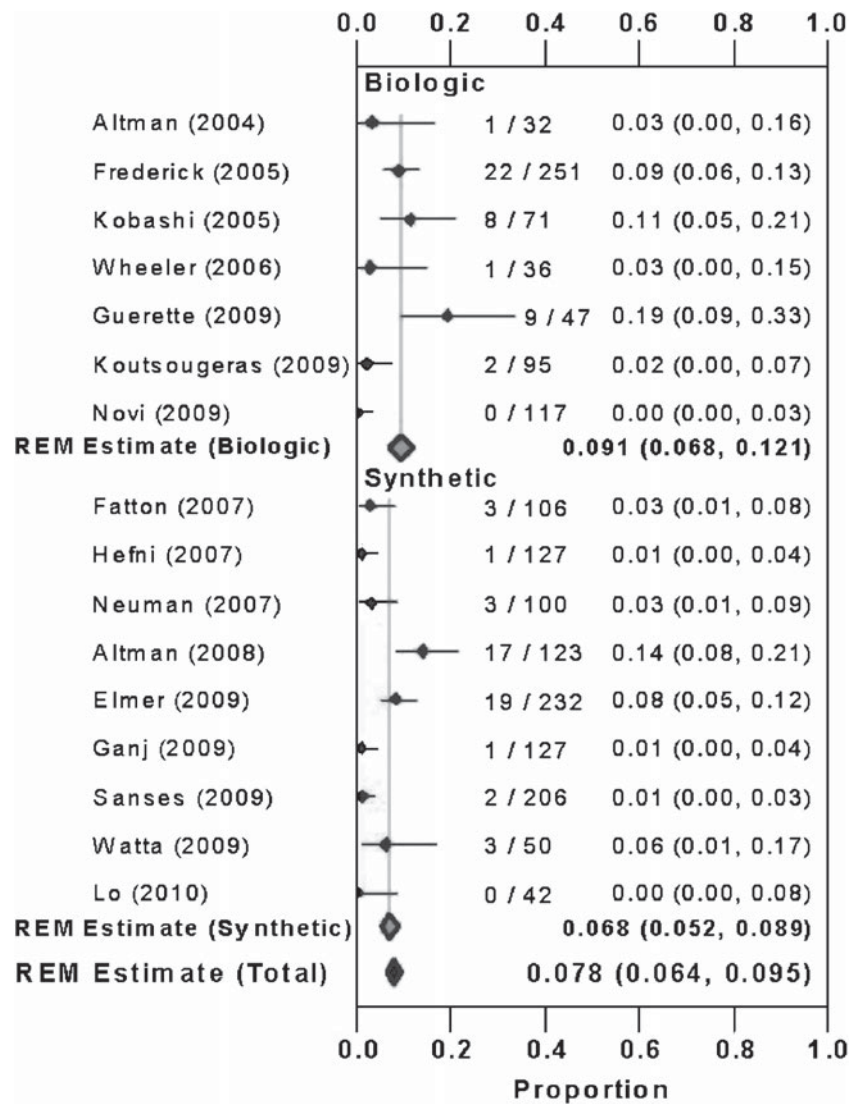
Similar incidence rates of erosion occurred using synthetic or biological grafts. However, most biological graft erosions were managed conservatively, while synthetic graft erosions often require operative revision. The available data suggest that graft erosions occur within 1 year of surgery and typically present with vaginal discharge, vaginal pain, and/or dyspareunia. However, few more erosions can be detected with longer follow-up, and there is a need to assess patients for graft exposure actively

at any time they are evaluated after their surgery. A provider should perform a focused and meticulous examination looking for this graft exposure, as many patients may be asymptomatic or mildly symptomatic but would not correlate their symptoms with this adverse event.

Two factors were repeatedly cited as risks for vaginal graft erosion: increasing patient age and concomitant hysterectomy and/or rectocele repair at the time of vaginal prolapse repair [9–11]. These risks factors are similar to what is known about risk factors for mesh exposure with abdominal or laparoscopic sacrocolpopexy, and many papers are not powered to detect significant differences regarding these risk factors. Many clinicians used vaginal estrogen with or without vaginal antibiotic therapy as an initial treatment for erosions. However, the majority of symptomatic mesh erosions (67%) required surgical excision either in the office or in the operating room.

Granulation tissue formation was reported in 7.8% with a wide range of occurrence across the studies (0 – 39%). This complication was more commonly reported following

**Fig. 3** Rates of wound granulation after biological and non-absorbable synthetic graft. Studies of women receiving grafts for vaginal prolapse in which adverse event rates were reported. For each study, the proportion and 95% confidence interval of women with the outcome are plotted. The *diamond* indicates the overall proportion of women with the outcome across the studies, by random effects model meta-analysis



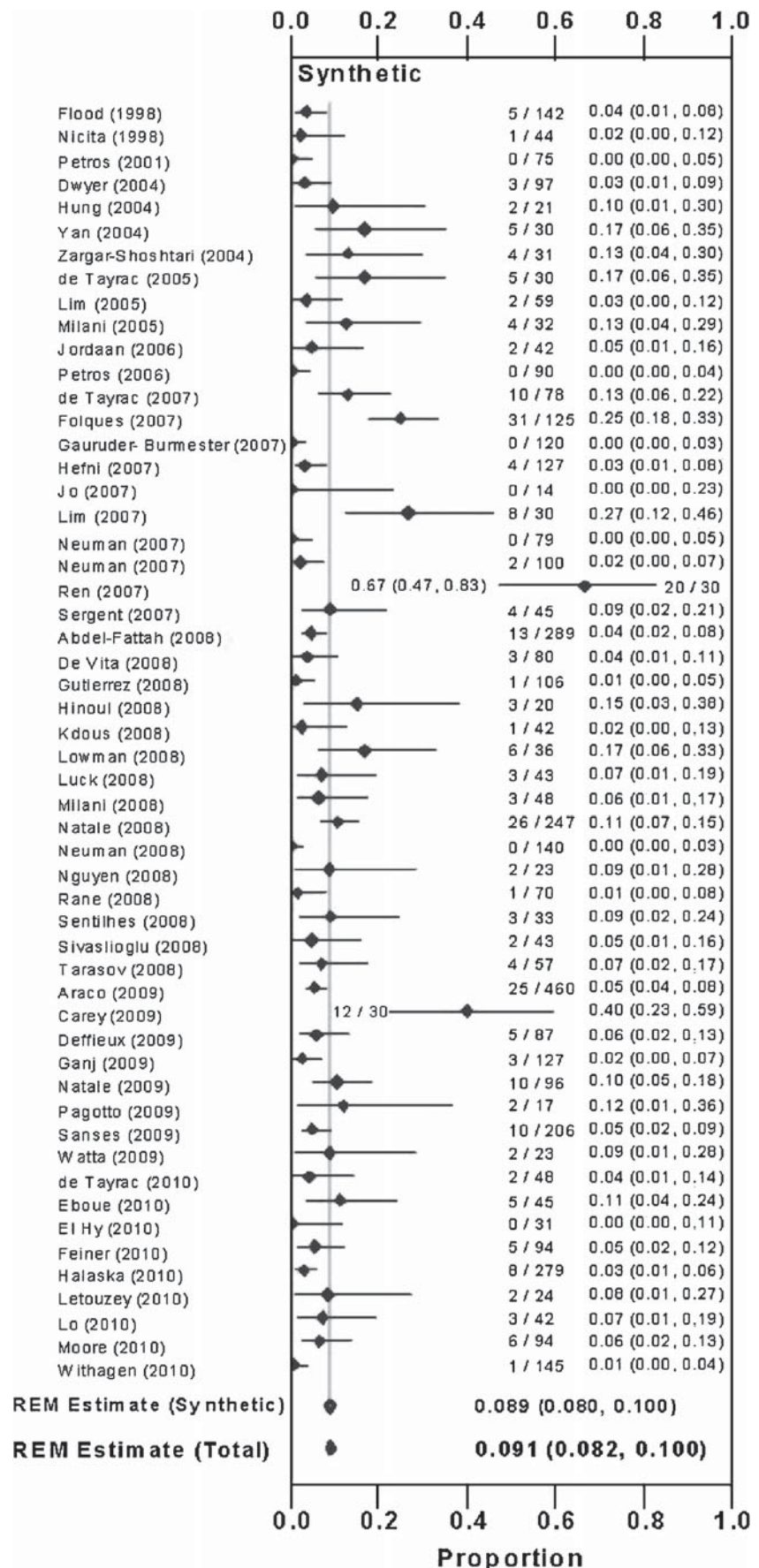
the use of biological grafts (9.1%) than in synthetic grafts (6.8%), though the difference was not statistically significant. Time to presentation of this granulation tissue formation was not consistently reported but was as little as 8 weeks postoperatively [23]. Most granulation appeared to result from exposed suture material—braided suture, in particular [7]. Some cases resolved spontaneously or after removal of exposed sutures in the office with application of silver nitrate [23, 24].

Studies reporting on dyspareunia following graft use were not consistent in reporting whether these incidence rates of dyspareunia are de novo or persistence of already existing pain. Overall, dyspareunia affected 9.1% of patients, with similar rates between biological and non-absorbable synthetic grafts (9.6% and 8.9%, respectively). However, these may be underestimations of the true dyspareunia rate, since some studies did not explicitly limit their analyses to sexually active women. In the few studies

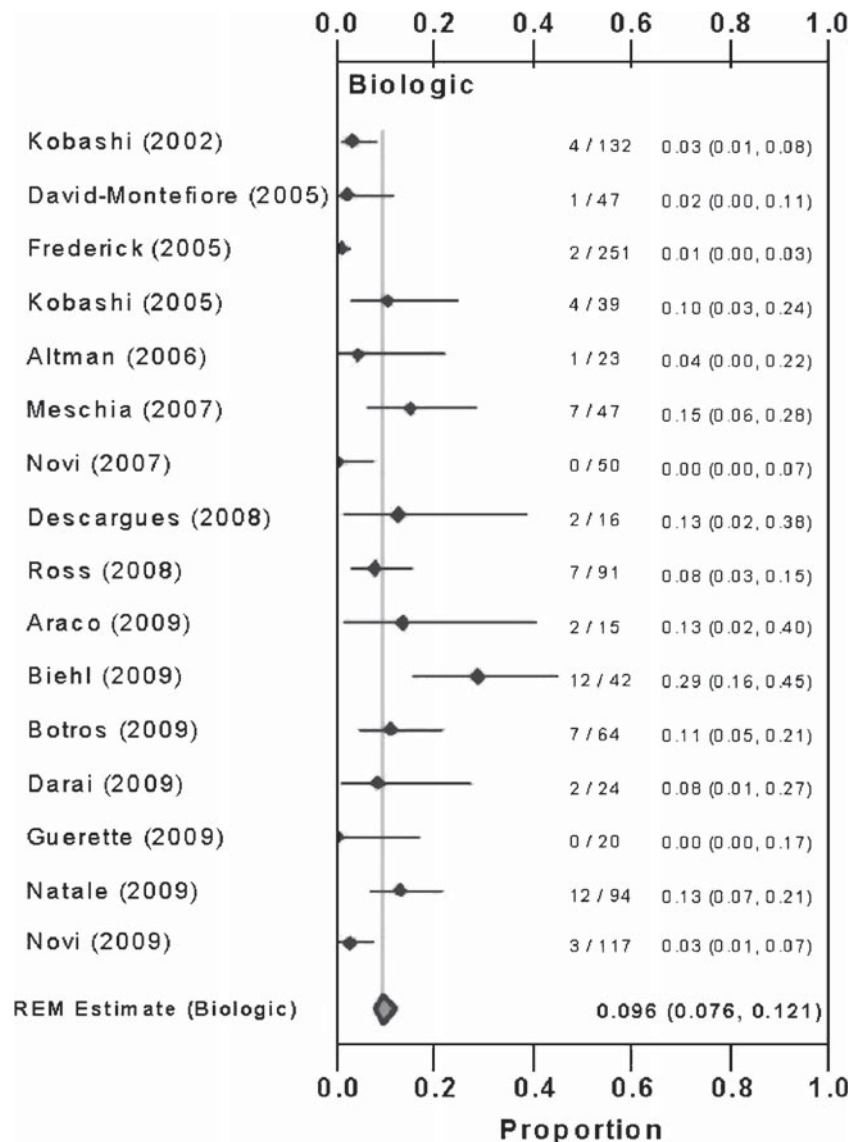
that attempted to identify how dyspareunia presented or possible risk factors for de novo pain, concomitant posterior repair [10, 11, 24] and/or mesh erosion [25–28] were common themes. Of course, dyspareunia may also occur with native tissue prolapse repairs, and it is unknown whether these incidence rates observed after graft augmentation are significantly higher than what would be expected with native tissue repairs.

The strength of this report is that it results from a comprehensive systematic review of the literature with well-defined outcomes; an attempt was made to collect all relevant published papers—with no language restrictions—to identify the spectrum of possible adverse events. The most significant limitation to an analysis of this kind is the body of literature from which it is made. In general, pelvic floor symptoms, sexual, bladder, and bowel dysfunction were poorly reported as were quality of life outcomes. Some studies described no differences in

**Fig. 4** Rates of dyspareunia after non-absorbable synthetic graft. Studies of women receiving non-absorbable synthetic grafts for vaginal prolapse in which adverse event rates were reported. For each study, the proportion and 95% confidence interval of women with the outcome are plotted. The *diamond* indicates the overall proportion of women with the outcome across the studies, by random effects model meta-analysis



**Fig. 5** Rates of dyspareunia after biological graft. Studies of women receiving biological grafts for vaginal prolapse in which adverse event rates were reported. For each study, the proportion and 95% confidence interval of women with the outcome are plotted. The *diamond* indicates the overall proportion of women with the outcome across the studies, by random effects model meta-analysis



functional outcomes (such as dyspareunia) between graft and no-graft treatment arms, but most published studies are underpowered to make such conclusions [3]. Most importantly, none of the studies could directly compare adverse event incidence between synthetic and biological grafts. The indirect comparisons across studies, as performed here, can never fully account for differences in populations, settings, and surgery unrelated to the choice of graft material. Randomized controlled trials of different graft materials are needed to reliably determine relative benefits and harms of the different grafts. Furthermore, it remains a question whether certain subgroups of women may be more likely to benefit from graft use in repairs or whether there are definitive risk factors for graft-related adverse events.

These limitations lead to recommendations for future research examining the benefits and harms of graft augmentation for vaginal prolapse repair. For future

randomized or observational studies, validated measures should be used to assess these adverse events at prescribed postoperative intervals. This lack of utilization of quality of life measures was very evident regarding measurement of the impact on sexual function. Most studies did not capture what proportion of women were sexually active, how many had preexisting sexual dysfunction, and how many experienced improvement in function. There was a trend toward improvement in collection of this information in the more recently published studies from the last 2 years, but this will be better assessed as more studies continue using available validated measures such as the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire [29]. Ideally, postoperative follow-up should be > 1 year, as most vaginal erosions appear to be captured within the first year after surgery. Furthermore, when reporting on graft complications, it is advised to follow the recommended terminology

by the joint International Urogynecological Association/International Continence Society Working Group on Complications Terminology. They recommended abandoning the term “erosion” and replacing with new terms:

*Exposure* A condition of displaying, revealing, exhibiting or making accessible (e.g., mesh exposure).

*Extrusion* Passage gradually out of a body structure or tissue.

In addition, better estimates of the frequency of uncommon adverse events will require more complete post-marketing surveillance or registries.

Finally, cystoscopy and rectal exams should be considered at the time of surgery as visceral injuries can occur, and without screening, these adverse events may be missed.

In October 2008, the US Food and Drug Administration (FDA) issued a Public Health Notification of the potential for serious complications associated with transvaginal placement of surgical mesh in repair of POP and stress urinary incontinence [30]. In the preceding 3 years, the FDA had received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and stress urinary incontinence. The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia. There were also reports of bowel, bladder, and blood vessel perforation during insertion.

The use of graft augmentation in prolapse repair came as a necessity from the significant failure rates with native tissue repairs. These native tissue repairs may be complicated by dyspareunia and granulation tissue formation in a similar manner to what occurs with graft-augmented repairs. This systematic review should help to further inform physicians on the incidences of these possible complications and should aid in counseling patients when gaining their informed consent for a planned surgical procedure.

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**Conflicts of interest** None.

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